James R. Condo (#005867)
Amanda C. Sheridan (#027360)
SNELL & WILMER L.L.P.
One Arizona Center
400 E. Van Buren, Suite 1900
Phoenix, AZ 85004-2204
Telephone: (602) 382-6000
jcondo@swlaw.com
asheridan@swlaw.com

Richard B. North, Jr. (admitted *pro hac vice*)
Georgia Bar No. 545599
Matthew B. Lerner (admitted *pro hac vice*)
Georgia Bar No. 446986
NELSON MULLINS RILEY & SCARBOROUGH LLP
Atlantic Station
201 17th Street, NW, Suite 1700
Atlanta, GA 30363
Telephone: (404) 322-6000
richard.north@nelsonmullins.com
matthew.lerner@nelsonmullins.com

Attorneys for Defendants
C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,

No. 2:15-MD-02641-DGC

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION IN LIMINE NO. 1

(Assigned to the Honorable David G. Campbell)

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively "Defendants" or "Bard") respond in opposition to Plaintiffs' Motion *in Limine* No. 1 by respectfully showing the Court as follows:

INTRODUCTION

The product at issue in this case is the Bard G2® Filter. The G2 Filter is a Class II medical device, which was cleared by FDA before Bard was permitted to market the device. A key issue in this case is whether the steps Bard took to bring the G2 Filter to market, including obtaining FDA clearance through the 510(k) process, were reasonable. Plaintiff's Motion *in Limine* No. 1 seeks to prejudice Bard by preventing it from presenting relevant evidence and thus from being able to provide a complete picture regarding the reasonableness of its actions.

Plaintiff erroneously asserts that just because a 510(k) clearance is not a definitive finding by FDA that a device is safe and effective, it "is irrelevant to the question of whether Bard's IVC filters are safe and effective" and whether "Bard has acted reasonably or its filters were not defective." (Pl.'s Mot. at 2.) FDA's mission, carried out in relevant part by its regulatory review of products, is to ensure that devices cleared for market are both safe and effective. While the level of regulatory review may vary depending on the Class of product involved, it is fundamentally wrong to suggest that the 510(k) clearance process does not consider safety and effectiveness. Indeed, this Court agreed that the "SMDA did introduce safety and effectiveness considerations into 510(k) review," even if the standard for those considerations is comparative. (Doc. 8872, at 12.) According to FDA, "***the principles of safety and effectiveness underlie the substantial equivalence determination in every 510(k) review***."[1]

As Bard demonstrated in its preemption briefing, (*see* Doc. 5396, 7828), FDA did consider the safety and efficacy of the G2 line of filters[2] before clearing them. For

[1] *See* FDA Guidance "*The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]*," issued July 28, 2014, at 6, attached hereto as Ex. "A."

[2] Bard's G2 line of filters includes the G2, G2® Express, and G2®X Filters. The G2 and G2 Express/G2X Filters are identical except that the G2 Express/G2X Filters include a snarable "hook" at the apex of the devices, which allows them to be retrieved via

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

example, before Bard could market the device as a permanent filter, FDA demanded specific safety and effectiveness information concerning Bard's *in vivo* animal studies. (*See* Doc. 5396, at 3.) FDA also mandated specific revisions to the labeling and even required Bard to change the trade name of the device for safety and effectiveness reasons. (*Id.*) Furthermore, given FDA's concerns about retrievability, FDA required Bard to conduct an IDE clinical trial called the EVEREST study. (*Id.*) FDA also requested that this clinical trial assess the product's safety performance, including, specifically, migration of the device. Between 2005 to 2008, Bard and FDA exchanged numerous communications concerning the status and progress of the EVEREST clinical trial. (*Id.* at 4.) FDA demanded information about adverse events observed during the trial. (*Id.*) Bard complied and also provided information to FDA regarding the clinical effectiveness and success of retrievability of the G2 Filter. (*Id.*) FDA reviewed all of the data from the clinical study and information concerning adverse events observed during the trial and cleared the G2 Filter as safe and effective for retrievability on January 15, 2008. (*Id.*)

Evidence related to the steps a manufacturer must take before a product is allowed on the market is highly relevant to a case involving an FDA regulated prescription product, like this one, particularly when Plaintiff claims it is defective and unreasonably dangerous. Compliance with federal regulatory standards, such as the 510(k) process, while not necessarily dispositive, is certainly probative under Georgia law on the issues of reasonableness of the design, manufacture, and warnings of the G2 Filter, as well as whether Bard's conduct rises to the level justifying punitive damages as Plaintiffs suggest.

ARGUMENT AND CITATION OF AUTHORITY

Evidence is relevant when it has "any tendency to make a fact more or less probable than it would be without the evidence." Fed. R. Evid. 401(a). One of the primary issues in this case is whether Bard acted reasonably in bringing the G2 Filter to market. While not conclusive, under Georgia law, Bard's efforts to comply with "federal . . .

---

commercially available surgical snares. The G2 Express and G2X Filters themselves are identical; however, they have minor changes to the delivery system.

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

regulatory restrictions" – such as the restriction from marketing a Class II device without 510(k) clearance, 21 C.F.R. § 807.81[3] – is directly probative of "the reasonableness of [Bard's] decision-making process" in designing the G2 Filter. *Banks v. ICI Americas Inc.*, 450 S.E.2d 671, 675 n.6 (Ga. 1994) (setting forth factors to consider under Georgia's risk-utility analysis, applicable to strict liability and negligent design defect claims). "Under the risk-utility test, compliance with federal standards or regulations is a factor for the jury to consider in deciding the question of reasonableness, that is, whether the product design selected was a reasonable one from among the feasible choices of which the manufacturer was aware or should have been aware." *Doyle v. Volkswagenwerk Aktiengesellschaft*, 481 S.E.2d 518, 521 (Ga. 1997) (citing *Banks*, 450 S.E.2d at 675). Indeed, compliance with federal regulations is a "significant" "piece of the evidentiary puzzle." *Id.*[4]

Additionally, a defendant's compliance with industry standards or government regulations is relevant to the issue of punitive damages. *See, e.g., Stone Man, Inc. v. Green*, 435 S.E.2d 205, 206 (Ga. 1993) (a manufacturer's "compliance with county, state, and federal regulations is not the type of behavior which supports an award of punitive damages"); *Barger v. Garden Way, Inc.*, 499 S.E.2d 737, 743 (Ga. Ct. App. 1998) ("[S]uch compliance does tend to show that there is no clear and convincing evidence of 'willful misconduct, malice, fraud, oppression, or that entire want of care which would raise the presumption of [a] conscious indifference to [the] consequences.").

Plaintiff's Motion ignores these principles of law. Instead, Plaintiff argues that

[3] *See generally* https://www.fda.gov/MedicalDevices/ DeviceRegulationandGuidance/ HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ (last visited Jan. 14, 2018) ("Before marketing a device, each submitter must receive an order, in the form of a letter, from FDA which finds the device to be substantially equivalent (SE) and states that the device can be marketed in the U.S. This order 'clears' the device for commercial distribution.").

[4] Other states follow the same rule. *See, e.g., Dorsey v. Honda Motor Co.*, 655 F.2d 650, 656 (5th Cir. Sept. 11, 1981) ("Generally speaking, compliance with regulatory standards may be admissible on the issue of care."); *Thomas v. Bombardier Recr. Prods., Inc.*, No. 2:07-CV-730-FTM-29, 2010 WL 4188308, at *4 (M.D. Fla. Oct. 20, 2010) ("Compliance with federal safety standards is generally relevant to negligence claims."); *Rader v. Teva Parental Meds., Inc.*, 795 F. Supp. 2d 1143, 1149 (D. Nev. 2011) (FDA compliance "relevant and admissible"); *Erony v. Alza Corp.*, No. 94 CIV. 5413 (DC), 1996 WL 554612, at *1 (S.D.N.Y. Sept. 30, 1996) ("[C]ompliance with the FDA's requests or directives may be considered . . . in determining whether defendants acted reasonably.").

evidence of Bard's compliance with FDA regulations, FDA's clearances of the G2 Filter, and FDA's lack of enforcement actions are somehow irrelevant because "[p]reviously, this Court recognized the 510(k) clearance process does not demonstrate safety or effectiveness." (Pl.'s Mot. at 2.)[5] As demonstrated more fully below, Plaintiff's argument is flawed, this evidence is highly relevant to the issues in this case, and admission will not result in either unfair prejudice to Plaintiff or mini-trials. But exclusion of this evidence will result in severe prejudice to Bard. Therefore, Plaintiff's Motion should be denied.

A. FDA's Clearance of the G2 Filter Is Relevant

Plaintiff's argument that evidence of FDA's clearance of the G2 line of filters is irrelevant is based on the erroneous assumptions that the relevance of evidence of Bard's regulatory compliance is restricted to federal "safety" regulations under Georgia law, and that safety and efficacy are unrelated to the 510(k) clearance process.

First, the Supreme Court of Georgia in *Banks v. ICI Americas Inc.*, 450 S.E.2d at 675 n.6, and *Doyle v. Volkswagenwerk Aktiengesellschaft*, 481 S.E.2d at 521, was clear that, under Georgia law, "compliance with federal standards or regulations is a factor for the jury to consider in deciding the question of reasonableness" under the risk-utility analysis. *Id.* The plain language of this controlling authority is broad, and not limited to federal "safety" standards or regulations. Georgia courts thereafter have followed this rule. *See, e.g.*, *Duren v. Paccar, Inc.*, 549 S.E.2d 755, 762 (Ga. Ct. App. 2001) ("[C]ompliance with federal standards or regulations is probative of [manufacturer's] reasonableness under the risk-utility analysis"); *Dean v. Toyota Indus. Equip. Mfg., Inc.*,

[5] In fact, Plaintiff goes so far as to contend that this Court has already decided the issue. (*See* Pl.'s Mot. at 2 ("[T]his Court found that 510(k) clearance is irrelevant to Plaintiffs' state law claims.").) But the Court did not address, let alone make a finding on, the relevancy of this evidence. Also, the Court cited *Cisson v. C. R. Bard, Inc.*, No. 2:11-cv-00195, 2013 WL 5700513, at *12 (S.D. W. Va. Oct. 18, 2013) merely to support the proposition that many cases find that 510(k) clearance does not preempt state tort law. (*See* Doc. 8872, at 11.) "This Court reached a similar conclusion in another case." (*Id.* at 11 n.7 (citing *Placencia v. I-Flow Corp.*, No. CV10-2520 PHX DGC, 2012 WL 5877624 (D. Ariz. Nov. 20, 2012)) In fact, in *Placencia*, this Court denied a motion *in limine* that sought to exclude evidence related to 510(k) clearance, holding that it could not conclude at that stage whether such evidence was "irrelevant to Plaintiff's state-law claims." *Placencia*, 2012 WL 5877624, at *8.

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

540 S.E.2d 233, 237 (Ga. Ct. App. 2000) ("A manufacturer's proof of compliance with federal regulations is also a factor to be considered [in making risk-utility analysis]."); *see, e.g.*, *Kelley v. Hedwin Corp.*, 707 S.E.2d 895, 899 (Ga. Ct. App. 2011) (affirming summary judgment on negligent design claim where there was evidence that product, among other things, "complied with government packaging and shipping regulations").[6]

Plaintiff's attempts to graft a "safety" limitation onto this rule are not supported by any controlling authority from the Supreme Court of Georgia or the Georgia Court of Appeals and should be rejected.[7] *See Winebarger v. Boston Sci. Corp.*, No. 5:15cv57-RLV, 2015 WL 5567678 (W.D.N.C. Sept. 21, 2015) (rejecting the plaintiffs' attempt to impute "safety" limitation into statute governing evidence of compliance with "any applicable government standard," as its plain meaning encompasses 510(k) clearance).

Nevertheless, as shown above, and in Bard's briefing on preemption (*see* Doc. 5396, 7828), safety and efficacy do play an important role in FDA's decision-making in the 510(k) clearance process. Indeed, this Court agreed that the "SMDA did introduce safety and effectiveness considerations into 510(k) review," even if the standard for those considerations is comparative. (Doc. 8872, at 12.) FDA itself summed it up best when it

[6] While *Doyle*, and other Georgia automobile manufacturing cases, dealt specifically with federal "Motor Vehicle Safety Standards," the *Doyle* court did not limit the relevance of compliance evidence to "safety" standards or regulations. 481 S.E.2d at 521 ("compliance with federal standards or regulations"). That these federal "safety" standards were sufficient to satisfy the "federal standards or regulation" rule does not mean that "safety" is a necessary condition under that rule. Regardless, "The FDCA and accompanying regulations are public safety regulations designed to protect consumers and patients such as the plaintiffs and the alleged harm from which they suffer." *Wheat v. Sofamor, S.N.C.*, 46 F. Supp. 2d 1351, 1362 (N.D. Ga. 1999).

[7] Although Plaintiff cites to some decisions by Judge Goodwin in West Virginia and by the Fourth Circuit involving Bard's surgical mesh products under Georgia law, (*see* Pl.'s Mot. at 2-5), those cases inappropriately imputed a "safety" limitation that is not supported by Georgia law. *See, e.g.*, *Cisson v. C.R. Bard, Inc.*, 86 F. Supp. 3d 510, 516 n.5 (S.D.W. Va. 2015) ("510(k) is not a safety regulation"), *aff'd sub nom.*, 810 F.3d 913 (4th Cir. 2016) ("[U]nder Georgia's risk-utility test the probative value of that evidence must depend on the extent to which the regulatory framework safeguards consumer safety"; finding merely no abuse of discretion under FRE 403, but declining to address "more difficult question presented by the Rule 402 ruling"); *see also In re C. R. Bard, Inc.*, No. 2:10-CV-01224, 2013 WL 11089794, at *1–2 n.2 (S.D.W. Va. July 1, 2013). The remaining cases were not based on, and are inconsistent with, Georgia law. *See, e.g.*, *Eghnayem v. Boston Sci. Corp.*, 873 F.3d 1304, 1318 (11th Cir. 2017) (applying Florida law). Further, the reasoning in those opinions is contrary to that of many other courts, as discussed below.

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

said that "the principles of safety and effectiveness underlie the substantial equivalence determination in every 510(k) review." *See* Ex. A, at 6.

The history of FDA's 510(k) clearance of the G2 line of filters -- as illustrated by FDA's own internal review memoranda -- shows that FDA reviewed the safety and efficacy of the products before clearing them. The exchange of information between Bard and FDA is relevant evidence that Bard took reasonable and appropriate steps in its efforts to bring the G2 Filter to market. Moreover, the fact that FDA cleared the G2 Filter is evidence, though not conclusive, to support Bard's claim that the filter is reasonably designed and, thus, not defective. Finally, the fact that FDA cleared the G2 line of filters on ***three separate occasions***[8] prior to when Plaintiff received her device in 2007 is relevant to demonstrate the reasonableness of Bard's decision to market the devices.

For these reasons, evidence of Bard's compliance with FDA regulations, and the FDA's decision to clear the G2 line of filters, is relevant in this case. *See Doyle*, 481 S.E.2d at 521 ("[C]ompliance with federal standards or regulations is a factor for the jury to consider in deciding the question of reasonableness, that is, whether the product design selected was a reasonable one from among the feasible choices."); *Stone Man, Inc.*, 435 S.E.2d at 206 ("[C]ompliance with county, state, and federal regulations is not the type of behavior which supports an award of punitive damages."); *see, e.g.*, *Block v. Woo Young Medical Co. Ltd.*, 937 F. Supp. 2d 1028, 1047 (D. Minn. 2013) (finding that evidence of the "FDA's general expectations" regarding a 510(k)-cleared device was admissible in a product liability action); *Pritchett v. I-Flow Corp.*, No. 09-cv-02433-WJM-KLM, 2012 WL 1340384 at * 5 (D. Colo. April 18, 2012) (regarding 510(k) cleared device, "whether Defendant complied with federal regulations is relevant to Plaintiff's negligence claim");

[8] FDA cleared the G2 Filter three times before Plaintiff's filter was placed -- in August 2005 (G2 Filter Permanent), *see* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K050558, in November 2005 (G2 Filter Jugular/Subclavian Delivery Kit), *see* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/ pmn.cfm?ID=K052578, and in October 2006 (G2 Filter Femoral Delivery Kit), *see* **Error! Hyperlink reference not valid.**. FDA cleared the G2 Filter again in January 2008 (G2 Filter Retrievable), *see* **Error! Hyperlink reference not valid.**, after her filter was placed.

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Musgrave v. Breg, Inc., No. 2:09-cv-01029, 2011 WL 4620767, at *3 (S.D. Ohio Oct. 3, 2011) (rejecting exclusion of evidence of 510(k) clearance, stating "Plaintiffs may argue about what it means, but they cannot keep the jury from hearing the fact that FDA cleared a general indication for use for the [product]").

B. *Medtronic, Inc. v. Lohr* Addressed Preemption – Not Evidentiary Standards

Plaintiff's reliance on *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), (*see, e.g.*, Pl.'s Mot. at 2), is misplaced. As this Court is aware, *Lohr* involved the question of whether FDA's clearance of a 510(k) device preempts state law product liability claims under 21 U.S.C. §360k(a). (*See* Doc. 8872, at 9.) The *Lohr* decision did not address whether evidence of FDA's 510(k) clearance of a device is admissible or relevant to whether a product is reasonably designed, or to determine the reasonableness of a manufacturer's actions. Moreover, while *Lohr* identified differences between the 510(k) process and the PMA process in reaching its preemption decision, the United States Supreme Court in a more recent decision clarified that, despite these differences, both are intended "to ensure . . . that medical devices are reasonably safe and effective." *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349-50 (2001).

Plaintiff's misplaced reliance on *Lohr*, which was decided twenty years ago, is underscored by the numerous courts that subsequent to *Lohr* have rejected the same argument in cases around the country. *See, e.g.*, *Block*, 937 F. Supp. 2d at 1047 (finding that evidence of the "FDA's general expectations" regarding a 510(k)-cleared device was admissible in a product liability action); *Pritchett*, 2012 WL 1340384, at *5 (in case involving 510(k) cleared device, "whether Defendant complied with federal regulations is relevant to Plaintiff's negligence claim"); *Musgrave*, 2011 WL 4620767, at *3 (rejecting the plaintiff's argument that evidence of 510(k) clearance should be excluded).

C. FDA's Lack of Enforcement Action Regarding Bard's G2 Filter Is Relevant

Plaintiff asks this court to exclude reference to FDA's lack of enforcement action regarding Bard's G2 line of filters. Plaintiff's position is erroneous for three reasons. *First*, the fact that the G2 line of filters was on the market for nearly 2 years before

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Plaintiff received her G2 filter and FDA did not bring an enforcement action against Bard regarding the products is relevant to whether it was reasonable for Bard to market the device in 2007. This is particularly true here, where Plaintiff argues that Bard should have withdrawn its IVC filters from the market. (*See* Doc. 8163, at 21). *Second*, given FDA's broad authority to investigate violations of the FDCA,[9] FDA's decision not to take any enforcement actions against Bard is probative as to whether Bard acted reasonably in its design and manufacture of the G2 line of filters. *Third*, Plaintiff is arguing that Bard somehow violated FDA regulations regarding its design, manufacture, and sale of the G2 line of filters. (*See* Doc. 8163, at 16, 23.) The fact that FDA has not taken an enforcement action against Bard with respect to the G2 line of filters -- notwithstanding FDA's power to do so in the face of violations of FDA regulations -- is evidence of whether Bard violated an FDA regulation, and, thus, directly probative to rebut Plaintiff's allegations.

D. FDA's Clearance of the G2 Filter and Lack of Enforcement Action Is Not Unfairly Prejudicial

Plaintiff fails to identify any legitimate basis for why she will be prejudiced if Bard is permitted to submit evidence of FDA clearance of the G2 line of filters. On the other hand, Bard will be extremely prejudiced in this case if it is not permitted to present to the jury the full circumstances concerning Bard's decision to initially market the G2 Filter in 2005, and then to continue to market the G2 line of filters through June 2007, when Plaintiff received her device. As explained above, during this time period, Bard was in frequent communication with FDA regarding the performance of the G2 Filter, was performing a clinical trial on the G2 Filter at FDA's request, and FDA thrice cleared Bard's G2 line of filters. Removing this evidence from the case creates an uneven playing field, leaving the jury with an incomplete picture concerning the reasonableness of Bard's actions. This is particularly true here, where one of Plaintiff's themes is that Bard allegedly violated FDA regulations and/or federal law. (*See* Doc. 8163, at 16, 23.)

[9] For example, FDA can impose sanctions, including injunctive relief, 21 U.S.C. §332, civil money penalties, §333(f)(1)(A), seizure of the device, §334(a)(2)(D), and criminal prosecution, 21 U.S.C. §333(a), 18 U.S.C. § 1001.

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

The prejudice that Plaintiff seeks to impose on Bard is amplified by the fact that Plaintiff herself seeks to present evidence at trial that Bard's G2 line of filters are somehow "adulterated" because the G2's predicate device, the Recovery® Filter, is allegedly not "substantially equivalent" to its predicate device, the Simon Nitinol Filter ("SNF"). (*See* Doc. 8163, at 23.) Plaintiff also seeks to present evidence that Bard never "implemented known design improvements to address filter migration and perforation" with the G2 line of filters, which she contends warrants punitive damages. (Doc. 8874, at 18-19.). In other words, Plaintiff would ask this Court to issue an order allowing Plaintiff to present evidence to the jury that Bard's G2 line of filters violate FDA's regulations based on comparisons to Bard's predicate device, and that Bard did not make design improvements from its later-generation filters, yet disallowing Bard from presenting evidence regarding the steps it took to demonstrate to FDA that its G2 line of filters should be legally marketed and FDA's multiple clearances of the devices, as well as "the extensive design, testing, and regulatory clearance processes that were required before any design changes could be implemented." (*Id.* at 21.) It would be fundamentally unfair, and would create a grossly uneven playing field, for Plaintiff's request to be granted.

Plaintiff's concern that she will be prejudiced because of a suggestion that FDA's 510(k) clearance of the device constitutes a finding by FDA of the device's safety and effectiveness can be alleviated by a limiting instruction and her own argument concerning the import of FDA's actions or inaction. *See Winebarger*, 2015 WL 5567578, at *7 (admitting evidence and noting that the jury can be instructed to avoid any prejudice). Like one court stated, Plaintiff is free to argue the implications, if any, of FDA's clearance of the G2 line of filters and lack of enforcement actions, but Plaintiff should not be allowed to keep such vital evidence from the jury. *See Musgrave*, 2011 WL 4620767, at *3 (rejecting the plaintiff's argument that evidence of 510(k) clearance should be excluded: "Plaintiffs may argue about what it means, but they cannot keep the jury from hearing the fact that FDA cleared a general indication for use for the [product]"). The jury expects to hear this evidence in a case involving a prescription medical device and both

sides have regulatory experts who can explain the FDA evidence to the jury.

Rather, the true prejudice comes from excluding this evidence, as it is undeniable that the G2 Filter, like every other prescription medical device in the United States, could not be marketed without prior FDA review, and excluding this information causes the jury to be left speculating about what happened. This FDA evidence is highly relevant and should be admitted at trial.

E. FDA's Clearance of the G2 Filter and Lack of Enforcement Action Will Not Result In A Mini-Trial

Plaintiff argues that allowing FDA evidence will result in a mini-trial on the 510(k) clearance process and whether Bard complied with FDA regulations. These perceived concerns were not borne out in the innumerable previous trials involving all sorts of prescription drug and devices, including 510(k) cleared medical devices, that have occurred in various jurisdictions. Rather, evidence regarding the 510(k) clearance process and Bard's compliance with FDA regulations will be part of the entire story in this case and is intertwined with Plaintiff's claims. This is how it has been done for decades in trials involving prescription drugs and medical devices.

Further, the product at issue in this case is the Bard G2 Filter—not the Recovery Filter, the SNF, or any of Bard's later-generation filters (e.g., the Eclipse®, Meridian®, or Denali® filters). Thus, the only FDA evidence relevant to this case is that related to the G2 Filter. Plaintiff points to Bard's preemption materials covering "the seven generation of filters at issue in this [MDL]" in an attempt to fabricate a problem that would not occur. (Pl.'s Mot. at 5.) Instead, it is Plaintiff, not Bard, who seeks to bring in irrelevant evidence regarding Bard's Recovery Filter and SNF at trial. Admission of FDA evidence relating to the G2 Filter will not result in a mini-trial. But admission of evidence related to the Recovery Filter and SNF, two devices that Plaintiff ***did not*** receive, necessarily will.

CONCLUSION

For these reasons, Bard respectfully requests that this Court deny Plaintiff's Motion *in Limine* No. 1.

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

RESPECTFULLY SUBMITTED this 17th day of January, 2018.

s/ Richard B. North, Jr.
Richard B. North, Jr.
Georgia Bar No. 545599
Matthew B. Lerner
Georgia Bar No. 446986
NELSON MULLINS RILEY & SCARBOROUGH, LLP
Atlantic Station
201 17th Street, NW / Suite 1700
Atlanta, GA 30363
PH: (404) 322-6000
FX: (404) 322-6050
richard.north@nelsonmullins.com
matthew.lerner@nelsonmullins.com

James R. Condo (#005867)
Amanda Sheridan (#027360)
SNELL & WILMER L.L.P.
One Arizona Center
400 E. Van Buren
Phoenix, AZ 85004-2204
PH: (602) 382-6000
jcondo@swlaw.com
asheridan@swlaw.com

Attorneys for Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc.

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

CERTIFICATE OF SERVICE

I hereby certify that on this 17th day of January, 2018, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

s/Richard B. North, Jr.
Richard B. North, Jr.

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000